510(k) Summary

ADMINISTRATIVE INFORMATION

Manufacturer Name: X-spine Systems, Inc.
452 Alexandersville Road
Miamisburg, OH 45342

Telephone (937) 847-8400
Fax (937) 847-8410

Official Contact: David Kirschman, M.D.
Chief Medical Officer

OCT 2 3 2013

Date Prepared: May 9, 2013

DEVICE NAME

Trade/Proprietary Name:	Calix ™ Lumbar Spinal Implant System
Common Name:	Intervertebral Body Fusion Device
Classification Name(s):	Intervertebral Fusion Device with Bone Graft, Lumbosacral
Device Class:	Class II
Product Code(s):	MAX
Regulation Number(s):	§888.3080

ESTABLISHMENT REGISTRATION NUMBER

The X-spine Systems, Inc. establishment registration number is 3005031160. The owner/operator number for X-spine Systems, Inc. is 9063903.

INTENDED USE

The X-spine Calix Lumbar Spinal Implant System is intended for spinal fusion procedures at one or two contiguous levels (L2 – S1 inclusive) in skeletally mature patients with degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the lumbosacral spine. DDD patients may also have up to a Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved level(s). These implants are to be packed with autogenous bone graft and implanted via an anterior, posterior, and/or transforaminal approach. Patients should receive at least six (6) months of non-operative treatment prior to treatment with a lumbosacral intervertebral fusion device.

This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).

DEVICE DESCRIPTION

The X-spine Calix Lumbar Spinal Implant System is a generally box or oval shaped device manufactured from Invibio PEEK-Optima LT1 per ASTM F2026 with an array of holes located throughout its geometry as well as teeth on the superior and inferior surfaces. The device is supplied in several widths and heights to accommodate variations in patient anatomy. The devices contain radiographic markers made from tantalum per ASTM F560.

The hollow center of the implant allows the device to be packed with bone graft.

EQUIVALENCE TO MARKETED PRODUCT

X-spine Systems, Inc. has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the Calix Lumbar Spinal Implant System is substantially equivalent in indications and design principles to predicate devices.

PREDICATE DEVICE(S)

- Medtronic Sofamor Danek – CAPSTONE Spinal System (K073291)
- Globus Medical, Inc. – Patriot Spacer System (K072970)
- Globus Medical, Inc. – Sustain & Sustain Radiolucent Spacers (K130478)
- K2M, Inc. – Aleutian Spinal System (K082698)
- Depuy Spine, Inc. – CONCORDE System (K081917)

PERFORMANCE DATA

To establish device performance, the following standardized tests were conducted on full device constructs:

ASTM F2077 – *Test Methods for Intervertebral Body Fusion Devices*

- Static and dynamic axial compression
- Static and dynamic axial compression-shear

ASTM F2267 – *Standard Test Methods for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device under Static Axial Compression*

Expulsion testing as suggested by FDA Guidance – *Class II Special Controls Guidance Document: Intervertebral Body Fusion Device*

BASIS OF SUBSTANTIAL EQUIVALENCE

In summary, biomechanical testing results indicate that the Calix Lumbar Spinal Implant System is substantially equivalent to predicate device performance and is as safe, as effective, and performs at least as safely and effectively as the cited predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 23, 2013

X-spine Systems, Incorporated
David Kirschman, M.D.
Chief Medical Officer
452 Alexandersville Road
Miamisburg, Ohio 45342

Re: K131350
Trade/Device Name: Calix™ Lumbar Spinal Implant System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: October 17, 2013
Received: October 18, 2013

Dear Dr. Kirschman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin F. Keith

Mark Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131350

Device Name: Calix™ Lumbar Spinal Implant System

Indications for Use:

The X-spine Calix Lumbar Spinal Implant System is intended for spinal fusion procedures at one or two contiguous levels (L2 – S1 inclusive) in skeletally mature patients with degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the lumbosacral spine. DDD patients may also have up to a Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved level(s). These implants are to be packed with autogenous bone graft and implanted via an anterior, posterior, and/or transforaminal approach. Patients should receive at least six (6) months of non-operative treatment prior to treatment with a lumbosacral intervertebral fusion device.

This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices